LEGEND: (Draft changes)

Single Underline = Draft new language

[Bold Print and Brackets] = Current language drafted for deletion

Regular Print = Current language

289.226 Registration of Radiation Machine Use and Services.

### (a) Purpose.

This section provides for the registration of persons using radiation machines and persons who are in the business of providing radiation machine installation or radiation services. No person shall use radiation machines or perform radiation services except as authorized in a certificate of registration issued by the agency in accordance with the requirements of this section. A person who receives, possesses, uses, owns, or acquires radiation machines prior to receiving a certificate of registration is subject to the requirements of this chapter.

### (b) Scope.

- (1) In addition to the requirements of this section, all registrants are subject to the requirements of §289.203 of this title (relating to Notices, Instructions, and Reports to Workers; Inspections), §289.204 of this title (relating to Fees for Certificates of Registration, Radioactive Material Licenses, Emergency Planning and Implementation, and Other Regulatory Services), §289.205 of this title (relating to Hearing and Enforcement Procedures), and §289.231 of this title (relating to General Provisions and Standards for Protection Against Machine-Produced Radiation).
- (2) Registrants using radiation machines in the healing arts [and veterinary medicine] are <u>also</u> subject to the requirements of §289.227 of this title (relating to Use of Radiation Machines in the Healing Arts [and Veterinary Medicine]).
- (3) Registrants using analytical, [and] other industrial radiation machines, such as x-ray equipment used for cathodoluminescence, ion implantation, gauging, or electron beam welding, and radiation machines for non-human use in morgues are also subject to the requirements of §289.228 of this title (relating to Radiation Safety Requirements for Analytical and Other Industrial Radiation Machines).
- (4) Registrants using accelerators, therapeutic radiation machines, and simulators are <u>also</u> subject to the requirements of §289.229 of this title (relating to Radiation Safety Requirements for Accelerators, Therapeutic Radiation Machines, and Simulators).
- (5) Registrants using mammography radiation machines are <u>also</u> subject to the requirements of §289.230 of this title (relating to Certification of Mammography Systems and Accreditation of Mammography Facilities).

- (6) Registrants using radiation machines in industrial radiographic operations are <u>also</u> subject to the requirements of §289.255 of this title (relating to Radiation Safety Requirements and Licensing and Registration Procedures for Industrial Radiography).
- (7) Registrants using dental radiation machines are subject to the requirements of §289.232 of this title (relating to Radiation Control Regulations for Dental Radiation Machines).
- (8) Registrants using veterinary radiation machines are subject to the requirements of §289.233 of this title (relating to Radiation Control Regulations for Veterinary Radiation Machines).
- (9) [(7)] Services listed in paragraph (10) [(8)] of this subsection may constitute the practice of medical physics and, therefore, may require individuals performing those services to have a license from the Texas Board of Licensure for Professional Medical Physicists in accordance with the Medical Physics Practice Act, Texas Occupations Code, Chapter 602.
- (10) For the purposes of this section, radiation services shall include, but may not be limited to the following:
- (A) performance of exposure rate or dose measurements to determine compliance with exposure rate or dose measurement requirements in this chapter;
- (B) gathering of radiation machine output measurements under the direction of a licensed medical physicist;
- (C) presentation of agency-accepted training courses that are specifically required by this chapter;
  - (D) calibration of survey and radiation measurement instruments:
- (E) demonstration and sales of radiation machines that require the individual to operate or cause a radiation machine to be operated in order to demonstrate or sell;
- (F) assembly, installation or repair to ensure a radiation machine is operating according to manufacturer's specifications;
- (G) completion of equipment performance evaluations on dental radiation machines;

Draft 1 226-2 August 2003

- (H) provision of radiation machines on a routine basis to a facility for limited time periods. For purposes of this section, a person providing the services described in this subparagraph is a provider of equipment. For healing arts facilities, the use of radiation machines shall be directed by a licensed practitioner employed by the contracting facility.
- [(8) For the purposes of this section, radiation services shall include, but may not be limited to the following:]
- [(A) provision of radiation protection or health physics consultations or surveys that require the consultant to operate or cause a radiation machine to be operated in order to make measurements or gather data;]
- [(B) presentation of agency-accepted training courses that are specifically required by this chapter;]
  - [(C) calibration of radiation machine output;]
  - [(D) calibration of survey and measurement instruments;]
- [(E) demonstration and sales of radiation machines that require the individual to operate or cause a radiation machine to be operated in order to demonstrate or sell;]
  - [(F) assembly, installation or repair];
  - [(G) provision of personnel monitoring services;]
  - [(H) performance of equipment performance evaluations; or]
- [(I) provision of radiation machines on a routine basis to a facility for limited time periods. For purposes of this section, a person providing the services described in this subparagraph is a provider of equipment. For healing arts facilities, the use of radiation machines shall be directed by a licensed practitioner employed by the contracting facility. For veterinary facilities, the use of radiation machines shall be directed by a licensed veterinarian employed by the contracting facility.]
- (11) **[(9)]** For purposes of this section, a practitioner of the healing arts is a person licensed to practice healing arts by either the Texas State Board of Medical Examiners as a physician, the Texas Board of Chiropractic Examiners, or the Texas State Board of Podiatry Examiners.
- (c) Prohibition. Exposure of an individual for training, demonstration, or other non-healing arts purposes is prohibited.

**Draft 1** 226-3 **August 2003** 

## (d) Exemptions.

- (1) Electronic equipment that produces radiation incidental to its operation for other purposes is exempt from the registration and notification requirements of this section, provided that the dose equivalent rate averaged over an area of 10 square centimeters (cm²) does not exceed 0.5 millirem per hour (mrem/hr) at 5 centimeters (cm) from any accessible surface of such equipment. The production, testing, or factory servicing of such equipment shall not be exempt.
- (2) Radiation machines in transit or in storage incident to transit are exempt from the requirements of this section. This exemption does not apply to the providers of radiation machines for mobile services. Facilities that have placed all radiation machines in storage, including on-site storage, and have notified the agency in writing, are exempt from the requirements of this section. This exemption is void if any radiation machine is energized resulting in the production of radiation.
- (3) Domestic television receivers, [and] video display terminals, and electron microscopes, including the servicing of such devices, are exempt from the requirements of this section.
- (4) Inoperable radiation machines are exempt from the requirements of this section. For the purposes of this section, an inoperable radiation machine means a radiation machine that cannot be energized when connected to a power supply without repair or modification.
- (5) Financial institutions that take possession of radiation machines as the result of foreclosure, bankruptcy, or other default of payment are exempt from the requirements in this section to the extent that they demonstrate that the unit is operable for the sole purpose of selling, leasing, or transferring.
- (6) Facilities, including academic institutions and research or [and/or] development facilities, registered for the use of radiation machines are exempt from the registration requirements of subsection (j) [subsections (g) and (l)] of this section to the extent that their personnel perform radiation services only for the facility by whom they are employed.

# (e) <u>General requirements for application</u> [Application] for registration.

(1) Application for registration shall be completed on forms prescribed by the agency and shall contain all the information required by the form and accompanying instructions.

Draft 1 226-4 August 2003

- (2) A radiation safety officer (RSO) shall be designated on each application form. The qualifications of that individual shall be submitted to the agency with the application. The RSO shall meet the applicable requirements of subsection  $\underline{(t)(1)}$  [(w)(1)] of this section and carry out the responsibilities of subsection  $\underline{(t)(2)}$  [(w)(2)] of this section.
- (3) The agency may at any time after the filing of the original application, require further statements in order to enable the agency to determine whether the certificate of registration should be issued or denied.
- (4) An application for a certificate of registration may include a request for a certificate of registration authorizing one or more activities. Applications for certification of mammography systems shall be made separately.
- (5) Applications and documents submitted to the agency may be made available for public inspection except that the agency may withhold any document or part thereof from public inspection in accordance with §289.231(aa) of this title.
- (6) Each application for a certificate of registration shall be accompanied by the fee prescribed in §289.204 of this title.
- (7) Each application shall be accompanied by a completed BRC Form 226-1 (Business Information Form). [BRC Form 226-1 (Franchise Tax Form) shall be submitted with the application to confirm that no tax owed to the state under Tax Code, Chapter 171, is delinquent.]
- (f) Application for registration for human **[or veterinary]** use of radiation machines. In addition to the requirements of subsection (e) of this section, each applicant shall comply with the following.
- (1) Each person having a radiation machine used in the healing arts [or veterinary medicine] shall apply for registration with the agency within 30 days after beginning use of the radiation machine, except for mobile services that shall be registered in accordance with subsection (g) [(i)] of this section, and healing arts screening and medical research programs that shall be approved in accordance with subsection (h) [(j)] of this section.
- (2) Each person having an accelerator or therapeutic radiation machine at or above 1 million electron volts (MeV) for human use shall apply for and receive a certificate of registration from the agency before energizing the accelerator, including performing acceptance testing. [activation, including acceptance testing, of the accelerator.]
- (3) Each person having a simulator and/or therapeutic radiation machine below 1 MeV for human use shall apply for registration with the agency within 30 days of energizing the equipment.

**Draft 1** 226-5 **August 2003** 

- (4) The applicant shall be qualified by reason of training and experience to use the radiation machine for the purpose requested in accordance with this section in such a manner as to minimize danger to occupational and public health and safety.
- (5) The applicant's proposed equipment, facilities, and operating and safety procedures shall be adequate to minimize danger to occupational and public health and safety.
- (6) An application for healing arts shall be signed by a licensed practitioner [and an application for veterinary medicine shall be signed by a licensed veterinarian]. The signature of the administrator, president, or chief executive officer will be accepted in lieu of a licensed practitioner's signature if the facility has more than one licensed practitioner who may direct the operation of radiation machines. The application shall also be signed by the RSO if the RSO is someone other than the licensed practitioner [or licensed veterinarian].
- (7) An application for accelerators or therapeutic radiation machines for human use shall be signed by a practitioner licensed by the Texas State Board of Medical Examiners. The signature of the administrator, president, or chief executive officer will be accepted in lieu of a licensed practitioner's signature if the facility has more than one licensed practitioner who may direct the operation of radiation machines. The application shall also be signed by the RSO if the RSO is someone other than the licensed practitioner. Each applicant shall submit operating and safety procedures as described in §289.229(h)(1)(D) of this title and a description of the proposed facilities in accordance with the following:
- (A) \$289.229(h)(2)(B) and (C) of this title for equipment with energies below 1 MeV; and
- (B) §289.229(h)(3)(B) of this title for equipment with energies above 1 MeV.
- (g) Application for registration of mobile services used in the healing arts. In addition to the requirements of subsections (e) and (f) of this section or §289.230(t) of this title, as applicable, each applicant shall apply for and receive authorization for mobile services before beginning mobile service operation. The following shall be submitted:
- <u>(1)</u> an established main location where the machine(s), records, etc. will be maintained for inspection. This shall be a street address, not a post office box number;
- (2) a sketch or description of the normal configuration of each radiation machine's use, including the operator's position and any ancillary personnel's location during exposures. If a mobile van is used with a fixed unit inside, furnish the floor plan indicating protective shielding and the operator's location; and

**Draft 1** 226-6 **August 2003** 

- applicant's operating and safety procedures regarding radiological practices for protection of patients, operators, employees, and the general public.
  - (h) Application for registration of healing arts screening and medical research.
- (1) In addition to the requirements of subsections (e) and (f) of this section, each applicant shall apply for and receive authorization for healing arts screening before initiating a screening program. The information and evaluation in subsection (t)(4) of this section shall be submitted with the application.
- (2) In addition to the requirements of subsections (e) and (f) of this section, any research using radiation machines on humans shall be approved by an Institutional Review Board (IRB) as required by Title 45, CFR, Part 46 and Title 21, CFR, Part 56. The IRB shall include at least one practitioner of the healing arts to direct any use of radiation in accordance with §289.231(b)(1) of this title.
- (i) Application for registration of radiation machines for non-human use, including use in morgues. In addition to the requirements of subsection (e) of this section, each applicant shall comply with the following.
- (1) Each person having an accelerator for non-human use shall apply for and receive a certificate of registration from the agency before beginning use of the accelerator.
- (2) Each person having an accelerator for non-human use shall submit the following:
- (A) operating and safety procedures as described in §289.229(f)(3)(B) of this title; and
- (3) Each person having a radiation machine for non-human use, other than those specified in paragraph (1) of this subsection and those used for industrial radiographic operations, shall apply for registration with the agency within 30 days after beginning use of the machine.
- (4) Each applicant for industrial radiographic operations shall submit the information required in §289.255(u)(7) of this title.

**Draft 1** 226-7 **August 2003** 

- (5) An application for the uses specified in this subsection shall be signed by the applicant or registrant or a person duly authorized to act for and on the applicant's or registrant's behalf. The application shall also be signed by the RSO if the RSO is someone other than the applicant or registrant.
- (j) [(g)] Application for registration of radiation machine <u>services</u>. [assembly, installation, calibration, or repair, consultants, providers of equipment and radiation services other than providers of personnel monitoring service, agency-accepted training courses, and calibration of survey and measurement instruments.] In addition to the requirements of subsection (e) of this section, each applicant shall comply with the following.
- (1) Each person who intends to provide radiation services described in subsection (b)(10) [(b)(8)] of this section shall apply for and receive a certificate of registration from the agency before providing such service.
- (2) An application for radiation services shall be signed by the applicant or registrant or a person duly authorized to act for and on the applicant's or registrant's behalf. The application shall also be signed by the RSO if the RSO is someone other than the applicant or registrant.
- (3) The applicant shall <u>submit written documentation to the agency</u> [submit to the agency written documentation] of the specific training and experience that qualifies each individual to discharge the duties of <u>RSO</u> [this service. Documentation of each individual's training shall be maintained for inspection by the agency.] As a minimum, each applicant shall submit the following:
- (A) for <u>assembly</u>, <u>installation</u>, <u>or repair</u> [assembler and/or calibration] of radiation machines, the qualifications listed in subsection (t)(3) [(w)(3)] of this section;
- (B) for individuals performing the services specified in subsection (b)(10)(A) of this section, a copy of the individual's license from the Texas Board of Licensure for Professional Medical Physicists;
- (C) [(B)] for all other services, the qualifications listed in subsection  $\underline{(t)(1)(A)(i)-(iii)}$  [(w)(1)(A)(i)-(iii)] of this section.
- (4) No person shall perform services specified in **[this]** subsection  $\underline{(b)(10)}$  of this section that are not specifically authorized by the agency.
- (5) No person shall perform  $\underline{\text{radiation}}$  [these] machine services, other than initial installation of the first  $\underline{\text{machine}(s)}$  [machine] on the premises, for an individual who cannot produce evidence of registration with the agency authorizing the possession and use of the machines in question.

**Draft 1** 226-8 **August 2003** 

- [(6) The applicant shall submit the interval to be followed to calibrate electronic equipment used in radiation machine servicing, for example, kVp meters and voltmeters.]
- (6) [(7)] Each applicant for providers of equipment shall <u>also</u> submit the following:
- (A) an established main location where the machines, records, etc. will be maintained for inspection. This shall be a street address, not a post office box number;
- (B) evidence that the healing arts facility responsible for administering or supervising the administering of radiation is registered in accordance with the requirements in this section; and
- (C) a current copy of the applicant's operating and safety procedures. A current copy of the applicant's operating and safety procedures is required when personnel are [also] provided in addition to equipment.
- (7) Each applicant for calibration of survey and radiation measurement instruments shall also submit the following:
  - (A) procedures for calibration;
  - (B) qualifications of personnel performing the calibration;
  - (C) a copy of the calibration certificate to be used; and
  - (D) a copy of the expiration sticker to be used.
- (8) Each applicant for agency-accepted training courses specifically required by §289.253 (relating to Radiation Safety Requirements for Well Logging Service Operation and Tracer Studies), and §289.255 of this title shall also submit the following:
  - (A) a course syllabus;
  - (B) the number of instructional hours for each subject;
- (C) a list of training resources, for example, reference books, texts, workbooks, physical facilities, etc.;
  - (D) all test questions and corresponding answers; and
- (E) the radiation safety training, education, and experience of each instructor.

- [(h) Application for registration for provider of personnel monitoring services. In addition to the requirements of subsection (e) of this section, each applicant shall comply with the following.]
- [(1) Each person who intends to provide personnel monitoring services shall apply for and receive a certificate of registration from the agency before providing such services.]
- [(2) An application for personnel monitoring services shall be signed by the applicant or registrant or a person duly authorized to act for and on the applicant's or registrant's behalf. The application shall also be signed by the RSO if the RSO is someone other than the applicant or registrant.]
- [(3) The applicant shall submit documentation that the facility has been accredited by the National Voluntary Laboratory Accreditation for Personnel Dosimetry Processors of the National Institute of Science and Technology in accordance with accreditation criteria established in Title 15, Code of Federal Regulations (CFR), Part 7b, as amended.]
- [(4) The maximum allowable time delay between the end date of the monitoring period and the date at which processing will not be performed shall be stated.]
- [(5) The maximum time between processing and reporting results shall be stated.]
- [(i) Application for registration of mobile services used in the healing arts and veterinary medicine. In addition to the requirements of subsections (e) and (f) of this section or §289.230(f) of this title, as applicable, each applicant shall apply for and receive authorization for mobile services before beginning mobile service operation. The following shall be submitted:]
- [(1) an established main location where the machine(s), records, etc. will be maintained for inspection. This shall be a street address, not a post office box number;]
- [(2) a sketch or description of the normal configuration of each radiation machine's use, including the operator's position and any ancillary personnel's location during exposures. If a mobile van is used with a fixed unit inside, furnish the floor plan indicating protective shielding and the operator's location; and]
- [(3) for mobile services used in the healing arts, a current copy of the applicant's operating and safety procedures regarding radiological practices for protection of patients, operators, employees, and the general public.]
- [(j) Application for registration of healing arts screening and medical research.]

**Draft 1** 226-10 **August 2003** 

- [(1) In addition to the requirements of subsections (e) and (f) of this section, each applicant shall apply for and receive authorization for healing arts screening before initiating a screening program. The information and evaluation in subsection (w)(4) of this section shall be submitted with the application.]
- [(2) In addition to the requirements of subsections (e) and (f) of this section, any research using radiation machines on humans shall receive prior approval from the agency and shall be approved by an Institutional Review Board (IRB) as required by Title 45, CFR, Part 46 and Title 21, CFR, Part 56. The IRB shall include at least one practitioner of the healing arts to direct any use of radiation in accordance with §289.231(b)(1) of this title.]
- [(k) Application for registration of radiation machines for non-human use other than veterinary medicine. In addition to the requirements of subsection (e) of this section, each applicant shall comply with the following.]
- [(1) Each person having an accelerator for non-human use shall apply for and receive a certificate of registration from the agency before beginning use of the accelerator.]
- [(2) Each person having an accelerator for non-human use shall submit the following:]
- [(A) operating and safety procedures as described in §289.229(f)(3)(C) of this title; and]
- [(B) a description of the applicant's proposed facilities in accordance with §289.229(f)(2) and (f)(3)(A), (B), and (D) of this title.]
- [(3) Each person having a radiation machine for non-human use other than veterinary medicine shall apply for registration with the agency within 30 days after beginning use of the machine.]
- [(4) Each applicant for industrial radiographic operations shall submit the information required in §289.255(u)(7) of this title.]
- [(5) An application for the uses specified in this subsection shall be signed by the applicant or registrant or a person duly authorized to act for and on the applicant's or registrant's behalf. The application shall also be signed by the RSO if the RSO is someone other than the applicant or registrant.]
- [(1) Application for registration of calibration of survey and measurement instruments. In addition to the requirements of subsection (e) of this section, each applicant shall comply with the following.]

**Draft 1** 226-11 **August 2003** 

- [(1) Each person who intends to engage in the business of providing calibration of survey and measurement instruments shall apply for and receive a certificate of registration from the agency before providing services.]
- [(2) An application for calibration of survey and measurement instruments shall be signed by the applicant or registrant or a person duly authorized to act for and on the applicant's or registrant's behalf. The application shall also be signed by the RSO if the RSO is someone other than the applicant or registrant.]
  - [(3) Each applicant shall submit the following:]
    - [(A) procedures for calibration;]
    - [(B) qualifications of personnel performing the calibration;]
    - [(C) a copy of the calibration certificate to be used; and]
    - [(D) a copy of the expiration sticker to be used.]
- [(m) Application for registration of agency-accepted training courses specifically required by this chapter. In addition to the requirements of subsection (e) of this section, each applicant shall comply with the following.]
- [(1) Each person who intends to engage in the business of providing agency-accepted training courses specifically required by this chapter shall apply for and receive a certificate of registration from the agency before providing training.]
- [(2) An application for agency-accepted training courses shall be signed by the applicant or registrant or a person duly authorized to act for and on the applicant's or registrant's behalf. The application shall also be signed by the RSO if the RSO is someone other than the applicant or registrant.]
  - [(3) Each applicant shall submit the following:]
    - [(A) a course syllabus;]
    - [(B) the number of instructional hours for each subject;]
- [(C) a list of training resources, for example, reference books, texts, workbooks, physical facilities, etc.;]
  - [(D) all test questions and corresponding answers; and]

**Draft 1** 226-12 **August 2003** 

- [(E) resumes containing the radiation safety training, education, and experience of each instructor.]
  - (k) [(n)] Issuance of certificate of registration.
- (1) Upon a determination that an application meets the requirements of the Texas Radiation Control Act (Act) and the requirements of the agency, the agency may issue a certificate of registration authorizing the proposed activity in such form and containing such conditions and limitations as it deems appropriate or necessary.
- (2) The agency may incorporate in the certificate of registration at the time of issuance, or thereafter by amendment, such additional requirements and conditions with respect to the registrant's possession, use, and transfer of radiation machines subject to this chapter as it deems appropriate or necessary in order to:
  - (A) minimize danger to occupational and public health and safety;
- (B) require additional reports and the keeping of additional records as may be appropriate or necessary; and
  - (C) prevent loss or theft of radiation machines subject to this section.
- (3) The agency may request and the registrant shall provide, additional information after the certificate of registration has been issued to enable the agency to determine whether the certificate of registration should be modified in accordance with subsection (r) of this section.
  - (1) [(o)] Specific terms and conditions of certificates of registration.
- (1) Each certificate of registration issued in accordance with this section shall be subject to the applicable provisions of the Act, now or hereafter in effect, and to the applicable rules and orders of the agency.
- (2) No certificate of registration issued or granted under this section shall be transferred, assigned, or in any manner disposed of, either voluntarily or involuntarily, to any person unless the agency authorizes the transfer in writing.
- (3) Each person registered by the agency for radiation machine use in accordance with this section shall confine use and possession of the radiation machine registered to the locations and purposes authorized in the certificate of registration.

**Draft 1** 226-13 **August 2003** 

- (4) "In making a determination whether to grant, deny, amend, renew, revoke, suspend, or restrict a certificate of registration, the agency may consider the technical competence and compliance history of an applicant or holder of a certificate of registration. After an opportunity for a hearing, the agency shall deny an application for a certificate of registration, an amendment to a certificate of registration, or renewal of a certificate of registration if the applicant's compliance history reveals that at least three agency or judicial orders have been issued against the applicant that assess administrative or civil penalties against the applicant, or that revoke or suspend the certificate of registration.
  - (m) **[(p)]** Responsibilities of registrant.
- (1) The registrant shall notify the agency in writing of any changes that would render the information contained in the application for registration and/or the certificate of registration inaccurate.
  - (A) Notification is required within 30 days of the following changes:
    - (i) name and mailing address;
    - (ii) street address where machine will be used;
    - (iii) RSO; or
    - (*iv*) type of servicing and/or services provided;
- (B) Each registrant shall inventory all radiation machines in their possession at an interval not to exceed one year. The inventory record shall be made and maintained for three years for inspection by the agency and shall include:
  - (i) manufacturer's name;
  - (ii) model and serial number of the control panel; and
  - (iii) location of radiation machine(s) (for example, room

number).

(C) [(A)] Notification is required within 30 days of any change of radiation machine inventory. This includes installation or removal and the disposition of any machine disposed of or transferred. [The assembler's notification of installation may be accepted in lieu of notification by the registrant with the exception of mammographic x-ray units. This does not relieve the registrant of the responsibility to assure that proper notification has been made.]

**Draft 1** 226-14 **August 2003** 

- (D) Each registrant shall maintain records of receipt, transfer, and disposal of radiation machines for inspection by the agency. The records shall include the following information and shall be kept until disposal is authorized by the agency:
  - (i) manufacturer's name;
  - (*ii*) model and serial number from the control panel;
  - (iii) date of the receipt, transfer, and disposal; and
  - (iii) name of the individual recording the information.
  - [(B) Notification is required within 30 days of the following changes:]
    - [(i) name and mailing address;]
    - [(ii) street address where machine will be used;]
    - [(*iii*) RSO; ]
    - [(*iv*) type of servicing and/or services provided;]
    - [(v) name of facility contracted for "provider of equipment."]
- (2) The following criteria applies to radiation machines used for clinical trial evaluations and loaner or demonstration radiation machines.
- [Radiation] machines used for clinical trial evaluations and loaner or demonstration radiation machines may be used for up to 60 days. [without adding the radiation machine to an existing certificate of registration. If the use period will exceed 60 days, the facility will be required to add the radiation machine to their certificate of registration and a fee will be assessed.] After 60 days, radiation [Radiation] machines shall be registered in accordance with subsection (f) [(f)(1)] of this section.
- (B) No fees will be assessed for the operation of radiation machines for clinical trial evaluations or loaner or demonstration radiation machines used for a period of 60 days or less at a facility with a current certificate of registration.
- (3) No registrant shall engage any person for services described in subsection (j) [(g)] of this section until such person provides evidence of registration with the agency.

**Draft 1** 226-15 **August 2003** 

- (4) Records of training and experience required by this section shall be maintained for inspection by the agency **[review]** until disposal is authorized by the agency.
- (5) The following applies to voluntary or involuntary petitions for bankruptcy.
- (A) Each registrant shall notify the agency, in writing, immediately following the filing of a voluntary or involuntary petition for bankruptcy by the registrant or its parent company. This notification shall include:
- (i) the bankruptcy court in which the petition for bankruptcy was filed; and
  - (ii) the date of the filing of the petition.
- (B) A copy of the "petition for bankruptcy" shall be submitted to the agency along with the written notification.
- (6) The registrant is responsible for complying with this chapter and the conditions of the certificate of registration.
- (7) No person shall use radiation machines or perform services that are not authorized in the certificate of registration issued by the agency.
  - (8) Assembler obligations are as follows.
- (A) No person shall transfer a radiation machine to or install for, other than initial installation of the first <u>machine(s)</u> [machine] on the premises, any person who does not possess a current certificate of registration issued by the agency in accordance with this section.
- (B) Any person who sells, leases, lends, disposes, assembles, installs, or otherwise transfers radiation machines in the state shall notify the agency of the following information within 30 days of such action:
- (*i*) the name, address, and certificate of registration number, except in the case of initial machine installation, of persons who have received such machines;
- (ii) the type of radiation machine, the manufacturer's name, model number, and control panel serial number of each radiation machine; and
  - (iii) the date of transfer or disposal of each radiation machine.

**Draft 1** 226-16 **August 2003** 

- (C) In the case of diagnostic x-ray systems that contain certified components, a copy of the assembler's report on United States Food and Drug Administration (FDA) form 2579, prepared in compliance with requirements of the federal diagnostic x-ray standard (Title 21, CFR, §1020.30(d)), shall be submitted to the agency within 30 [15] days following completion of the assembly. Such report shall suffice in lieu of any other assembly report submitted by the assembler to the agency.
- (D) No person shall make, sell, lease, transfer, lend, assemble, or install radiation machines or the components of such machines unless such machines and equipment, when properly placed in operation and used, meet the applicable requirements of this chapter.
- (9) Providers of equipment shall keep a log of radiation machines provided in Texas. The record shall be maintained for five years for inspection by the agency and shall list the following current information:
  - (A) date machine is provided; and
- (B) name of customer and customer's certificate of registration number.
- (n) [(q)] Sale, lease, loan, installation, assembly, disposal, and transfer of radiation machines.
- (1) No person shall transfer a radiation machine to or install for, other than initial installation of the first machine on the premises, any person who does not possess a current certificate of registration issued by the agency in accordance with this section.
- (2) Any person who sells, leases, lends, disposes, assembles, installs, or otherwise transfers radiation machines in the state shall notify the agency of the following information within 30 days of such action:
- (A) the name, address, and certificate of registration number, except in the case of initial machine installation, of persons who have received such machines;
- (B) the type of radiation machine, the manufacturer's name, model number, and control panel serial number of each radiation machine; and
  - (C) the date of transfer or disposal of each radiation machine.
- (3) No person shall make, sell, lease, transfer, lend, assemble, or install radiation machines or the components of such machines unless such machines and equipment, when properly placed in operation and used, meet the applicable requirements of this chapter.

**Draft 1** 226-17 **August 2003** 

- (o) [(r)] Expiration of certificates of registration and fee renewal.
- (1) Effective September 1, 2004, the term of the certificate of registration is two years. Except as provided by subsection (q) of this section, each certificate of registration expires at the end of the day, in the month and year stated in the certificate of registration. Upon payment of the fee required by §289.204 of this title and if the agency does not deny the renewal in accordance with subsections (l)(4) of this section, the certificate of registration will be renewed. [Except as provided by subsection (t) of this section, each certificate of registration that specifies an expiration date expires at the end of the day on that date Expiration of the certificate of registration does not relieve the registrant of the requirements of this chapter.]
- (2) Expiration of the certificate of registration does not relieve the registrant of the requirements of this chapter.
- (3) [(2)] If a registrant does not pay the fee required by §289.204 of this title and the certificate of registration is not renewed, [submit an application for renewal of the certificate of registration under subsection (t) of this section, as applicable,] the registrant shall on or before the expiration date specified in the certificate of registration:
- (A) terminate use of all radiation machines and/or terminate radiation machine servicing or radiation services;
- (C) pay any outstanding fees in accordance with §289.204 of this title.
- (p) [(s)] Termination of certificates of registration. When a registrant decides to terminate all activities involving radiation machines or services authorized under the certificate of registration, the registrant shall [notify the agency] immediately [and] do the following:
  - (1) request termination of the certificate of registration in writing;
- (2) submit  $\underline{\text{to the agency}}$  a record of the disposition of the radiation machines, if applicable; and
  - (3) pay any outstanding fees in accordance with §289.204 of this title.
  - (q) [(t)] <u>Technical renewal</u> [Renewal] of certificate of registration.

- (1) Application for <u>a</u> renewal <u>in entirety of a certificate of</u> registration shall be filed in accordance with subsection (e)(1)-(5) of this section [,] <u>and</u> applicable paragraphs of subsections (f), (i), and (j) [(f), (h), and (k)-(m)] of this section [, and §289.230 of this title, as applicable]. Application for a renewal in entirety of a certificate of registration shall be submitted to the agency by the date specified in the existing certificate of registration condition. If the registrant fails to apply, the certificate of registration expires and the registrant shall comply with the requirements of subsection (o)(3)(A)-(C) of this section.
- (2) If a registrant files an application for a renewal <u>in entirety</u> in proper form before the existing certificate of registration expires, such existing certificate of registration shall not expire until the application status has been determined by the agency.
  - (r) **[(u)]** Modification and revocation of certificates of registration.
- (1) The terms and conditions of all certificates of registration shall be subject to [amendment,] revision [,] or modification. A certificate of registration may be suspended or revoked by reason of amendments to the Act, [or] by reason of rules in this chapter or [and] orders issued by the agency.
- (2) Any certificate of registration may be revoked, suspended, or modified, in whole or in part, for any of the following:
- (A) any material false statement in the application or any statement of fact required under provisions of the Act;
- (B) conditions revealed by such application or statement of fact or any report, record, or inspection, or other means that would warrant the agency to refuse to grant a certificate of registration on an original application; [or]
- (C) violation of, or failure to observe any of the terms and conditions of the Act, this chapter, [or of] the certificate of registration, or order of the agency; or [.]
- (D) existing conditions that constitute a substantial threat to the public health or safety or the environment.
- (3) Each certificate of registration revoked by the agency ends at the end of the day on the date of the agency's final determination to revoke the certificate of registration, or on the revocation date stated in the determination, or as otherwise provided by the agency order.
- (4) Except in cases **[of willfulness or those]** in which the occupational and public health, interest or safety requires otherwise, no certificate of registration shall be modified, suspended, or revoked unless, prior to the institution of proceedings therefore, facts

**Draft 1** 226-19 **August 2003** 

or conduct that may warrant such action shall have been called to the attention of the registrant in writing and the registrant shall have been afforded an opportunity to demonstrate compliance with all lawful requirements.

- (s) [(v)] Reciprocal recognition of out-of-state certificates of registration.
- (1) Whenever any radiation machine is to be brought into the state for any temporary use, the person proposing to bring the machine into the state shall apply for and receive a notice from the agency granting reciprocal recognition prior to beginning operations. The request for reciprocity shall include the following:
- (A) completed BRC Form 226-1 (Business Information Form) [(Franchise Tax Form)];
- (B) completed BRC Form 252-3 (Notice of Intent to Work in Texas Under Reciprocity);
- (C) completed qualification forms (BRC Forms 255-E, 255-T and/or 255-OS) for each radiographer who will be working in Texas if the reciprocity request is for industrial radiography;
- (D) name and Texas licensing board number of the practitioner if the machines are used to irradiate humans;
- [(E) name and Texas licensing board number of the veterinarian if the machines are used to irradiate animals;]
- (E) [(F)] copy of the applicant's current [state] certificate of registration or equivalent document;
- $\underline{(F)}$  [(G)] copy of the applicant's current operating and safety procedures pertinent to the proposed use; [and]
  - (G) [(H)] [annual] fee as specified in §289.204(e) of this title; and [.]
  - (H) qualifications of personnel who will be operating the machines.
- (2) Upon a determination that the request for reciprocity meets the requirements of the agency, the agency may issue a notice granting reciprocal recognition authorizing the proposed use.

**Draft 1** 226-20 **August 2003** 

- (3) Once reciprocity is granted, the out-of-state registrant shall file a BRC Form 252-3 with the agency prior to each entry into the state. This form shall be filed at least three working days before the radiation machine is to be used in the state. If, for a specific case, the three-day period would impose an undue hardship, the out-of-state registrant may, at the determination of the agency, obtain permission to proceed sooner.
- (4) When radiation machines are used as authorized under reciprocity, the out-of-state registrant shall have the following in its possession at all times for inspection by the agency:
  - (A) completed BRC Form 252-3;
  - (B) copy of the notice from the agency granting reciprocity;
- (C) copy of the out-of-state registrant's operating and safety procedures; and
- (D) copy of the applicable rules as specified in the notice granting reciprocity.
- (5) If the state from which the radiation machine is proposed to be brought does not issue certificates of registration or equivalent documents, a certificate of registration shall be obtained from the agency in accordance with the requirements of this section.
- (6) The agency may withdraw, limit, or qualify its acceptance of any certificate of registration or equivalent document issued by another agency upon determining that such action is necessary in order to prevent undue hazard to occupational and public health and safety or property.
- (7) Reciprocal recognition will expire one year from the date it is granted. A new request for reciprocity shall be submitted to the agency each year. Reciprocity requests made after the initial request shall include only the following:
  - (A) completed BRC Form 226-1 (Business Information Form);
- (B) completed BRC Form 252-3 (Notice of Intent to Work in Texas Under Reciprocity);
- (C) completed qualification forms (BRC Forms 255-E, 255-T and/or 255-OS) for each radiographer who will be working in Texas if the reciprocity request is for industrial radiography;
- (D) name and Texas licensing board number of the practitioner if the machines are used to irradiate humans;

- $\underline{(F)}$  copy of the applicant's current operating and safety procedures pertinent to the proposed use;
  - (G) fee as specified in §289.204(e) of this title; and
  - (H) qualifications of personnel who will be operating the machines.
  - [(A) completed BRC Form 226-1;]
  - [(B) completed BRC Form 252-3;]
  - [(C) fee as specified in §289.204(e) of this title.]
- (8) Radiation services provided by a person from out-of-state will not be granted reciprocity. Whenever radiation services are to be provided by a person from out-of-state, that person shall apply for and receive a certificate of registration from the agency before providing radiation services. The application shall be filed in accordance with subsections (e), (j), and (i) [(e), (g)-(h), and (k)-(m)] of this section, as applicable.

## (t) [(w)] Appendices.

- (1) Requirements for RSOs for registrants.
- (A) All RSOs shall meet the following general requirements in addition to requirements in specific categories, except for industrial radiography RSOs:
- (i) knowledge of potential radiation hazards or emergency precautions; and
- (ii) educational courses related to ionizing radiation safety or a radiation safety officer course; or
- (iii) experience in the use and familiarity of the type of equipment used.
- (i) educational courses related to ionizing radiation safety or a radiation safety officer course;
- [(ii)] experience in the use and familiarity of the type of equipment used; and

Draft 1 226-22 August 2003

# [(iii) knowledge of potential radiation hazards or emergency precautions.]

- (B) Specific requirements for RSOs by facility are as follows.
  - (i) Healing arts facilities shall have:
- (I) licensed practitioner RSOs with documentation of licensing board number; or
  - (*II*) non-practitioner RSOs with the following:

(-a-) evidence of a valid general certificate issued under the Medical Radiologic Technologist Certification Act, Texas Occupations Code, Chapter 601, and at least two years of supervised use of radiation machines;

(-b-) evidence of a valid limited general certificate issued under the Medical Radiologic Technologist Certification Act, Texas Occupations Code, Chapter 601, and at least four years of supervised use of radiation machines:

(-c-) evidence of registry by the American Registry of Radiologic Technologists (ARRT) or the American Registry of Clinical Radiologic Technologists (ARCRT) and at least two years of supervised use of radiation machines;

(-d-) evidence of associate degree in radiologic technology, health physics, or nuclear technology, and at least two years of supervised use of radiation machines;

(-e-) evidence of registration with the Board of Nurse Examiners as a Registered Nurse or a Registered Nurse with an extended scope of practice (Nurse Practitioner) performing radiologic procedures, and at least two years of supervised use of radiation machines in the respective practitioners' specialty;

(-f-) evidence of registration with the Texas State Board of Physician Assistant Examiners, and at least two years of supervised use of radiation machines in the respective practitioners' specialty;

### (-g-) evidence of:

(-1-) registration with the Texas State Board of Medical Examiners performing radiologic procedures under a physician's instruction and direction; (-2-) registration with the Texas State Board of Chiropractic Examiners performing radiologic procedures under a chiropractor's instruction and direction; or

(-3-) registration with the Texas State Board of Podiatry Examiners performing radiologic procedures under a podiatrist's instruction and direction; and

(-4-) at least four years of supervised use of radiation machines in the respective practitioners' specialty;

(-h-) for radiotherapy facilities, evidence of registry by the ARRT or ARCRT and at least four years of supervised experience in radiotherapy;

(-i-) evidence of bachelor's (or higher) degree in a natural or physical science, health physics, radiological science, nuclear medicine, or nuclear engineering; or

(-j-) evidence of a current Texas license under the Medical Physics Practice Act, Texas Occupations Code, Chapter 602, in one or more of the following appropriate specialties:

(-1-) medical health physics, diagnostic radiological physics, or medical nuclear physics for diagnostic x-ray facilities; or

(-2-) medical health physics or therapeutic radiological physics for radiotherapy facilities.

# [(ii) Veterinary facilities shall have:]

[(1) veterinarian RSOs with documentation of veterinary license board number; or]

[(II) non-veterinarian RSOs with two years minimum experience in the use of radiation machines in veterinary medicine under the supervision of a licensed veterinarian.]

(ii) [(iii)]Academic institutions and/or research and development facilities shall have RSOs who are faculty or staff members in radiation protection, radiation engineering, or related disciplines. (This individual may also serve as the RSO over the healing arts section of the facility.)

**Draft 1** 226-24 **August 2003** 

(iii) [(iv)]Industrial radiography operations shall have RSOs who meet the requirements of \$289.255(m)(4)(B) of this title.

- (C) Exemptions. The RSO identified on a certificate of registration issued before September 1, 1993, need not comply with the training requirements in this subsection.
- (2) Responsibilities of RSOs. Specific duties of the RSO include, but are not limited to, the following:
- (A) establishing and overseeing operating and safety procedures that maintain radiation exposures as low as reasonably achievable (ALARA), and to review them regularly to ensure that the procedures are current and conform with this chapter;
- (B) ensuring that individual monitoring devices are properly used by occupationally-exposed personnel, that records are kept of the monitoring results, and that timely notifications are made as required by §289.203 of this title;
- (C) investigating and reporting to the agency each known or suspected case of radiation exposure to an individual or radiation level detected in excess of limits established by this chapter and each theft or loss of source(s) of radiation, determining the cause, and taking steps to prevent its recurrence;
- (D) having a thorough knowledge of management policies and administrative procedures of the registrant and keeping management informed on a periodic basis of the performance of the registrant's radiation protection program, if applicable;
- (E) assuming control and having the authority to institute corrective actions including shut-down of operations when necessary in emergency situations or unsafe conditions;
  - (F) maintaining records as required by this chapter;
- (G) ensuring that personnel are adequately trained and complying with this chapter, the conditions of the certificate of registration, and the operating and safety procedures of the registrant.
- (3) Minimum education and training for persons performing radiation machine assembly, installation or repair. All persons performing radiation machine assembly, installation or repair shall meet the general requirements in subparagraph (A) of this paragraph and one or more of the specialized requirements in subparagraph (B) of this paragraph.
  - (A) General requirements include:

- (*i*) experience or education providing familiarity with the type(s) of equipment to be serviced, to include radiation safety;
- (ii) knowledge of protective measures to reduce potentially hazardous conditions; and
- (iii) six months of supervised assembly and repair of the type(s) of equipment to be serviced.

### (B) Specialized requirements include:

- (*i*) one year of formal training (may be satisfied by factory school, military technical training school, or other courses in radiation machine assembly, installation or repair techniques) or an associate's degree in biomedical equipment repair;
- (ii) a bachelor's degree in electrical engineering with specialized training in radiation producing devices; or
- (iii) a combination of training and experience equal to clause (i) of this subparagraph.
- (C) Exemptions. A registrant holding a valid certificate of registration who has hired individuals to perform services before September 1, 1993, need not comply with the education and training requirements in this paragraph. Individuals hired after September 1, 1993, shall comply with the education and training requirements in this paragraph.
- (4) Information to be submitted by persons proposing to conduct healing arts screening. Persons requesting that the agency approve a healing arts screening program shall submit the following information and evaluation.

#### (A) Administrative controls to include the following:

- (*i*) the name and address of the applicant and, where applicable, the names and addresses of agents within Texas;
- (ii) the diseases or conditions for which the x-ray examinations are to be used in diagnoses;
- (iii) a detailed description of the x-ray examinations proposed in the screening program;

**Draft 1** 226-26 **August 2003** 

- (*iv*) a description of the population to be examined in the screening program, for example, age, sex, physical condition, and other appropriate information; [and]
- ( $\nu$ ) an evaluation of any known alternate methods not involving ionizing radiation that could achieve the goals of the screening program and why these methods are not used instead of the x-ray examination; and  $\Gamma$ .
- (*vi*) for mobile screening operations, location(s) where radiation machines are used and maintained.
- (B) Operating procedures for all x-ray systems (except bone densitometers) to include the following:
- (*i*) an evaluation of the x-ray systems to be used in the screening program. The evaluation shall be performed by a licensed medical physicist with a specialty in diagnostic radiological physics. The evaluation shall show that such systems do satisfy all requirements of this section;
- (ii) a description of the diagnostic <u>imaging</u> [film] quality control program; and
- (iii) a copy of the technique chart for the x-ray examination procedures to be used.
- (C) Operating procedures for bone densitometers to include the manufacturer's evaluation of the system to be used in the screening program. The evaluation shall show that such systems satisfy all requirements of this section.
  - (D) Training data to include the following:
- (*i*) the qualifications of each individual who will be operating the x-ray systems;
- (*ii*) the qualifications of the individual who will be supervising the operators of the x-ray systems. The extent of supervision and the method of work performance evaluation shall be specified; and
- (*iii*) the name and address of the practitioner <u>licensed in Texas</u> who will interpret the radiographs.
  - (E) Records to include the following:

- (i) a description of the procedures to be used in advising the individuals screened, and their private practitioners of the healing arts, of the results of the screening procedure and any further medical needs indicated; and
- (ii) a description of the procedures for the retention or disposition of the radiographs and other records pertaining to the x-ray examinations.

**Draft 1** 226-28 **August 2003**